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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/656,647   | 09/04/2003  | Robert A. VanTassel  | 4056                | 8112             |
| 21834  | 7590        | 09/16/2010           |                     |                  |
| BECK AND TYSVER P.L.L.C.<br>2900 THOMAS AVENUE SOUTH<br>SUITE 100<br>MINNEAPOLIS, MN 55416 |             |                      | EXAMINER            |                  |
|  |             |                      | BUL, VY Q           |                  |
|  |             |                      | ART UNIT            | PAPER NUMBER     |
|  |             |                      | 3773                |                  |
|  |             |                      |                     |                  |
|  |             |                      | MAIL DATE           | DELIVERY MODE    |
|  |             |                      | 09/16/2010          | PAPER            |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |   |
|------------------------------|--------------------------------------|---|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/656,647 | <b>Applicant(s)</b><br>VANTASSEL ET AL. |
|                              | <b>Examiner</b><br>Vy Q. Bui         | <b>Art Unit</b><br>3773                 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If no period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 4/5/2010.  
 2a) This action is FINAL.      2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-7 is/are pending in the application.  
 4a) Of the above claim(s) 2 and 3 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1 and 4-7 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)  
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) Information Disclosure Statement(s) (PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_

4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date \_\_\_\_\_  
 5) Notice of Informal Patent Application  
 6) Other: \_\_\_\_\_

**DETAILED ACTION**

In view of the "Appeal Brief" filed on 4/5/2010, PROSECUTION IS HEREBY REOPENED.

The new ground of rejection is set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

***Election/Restrictions***

Claims 2-3 withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 3/1/2007.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 (line 12) recites "blood may flow through the filtering membrane". It is not clear if blood will actually flow through the filtering membrane or not. Clarification is required.

***Claim Rejections - 35 USC § 102***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1, 4-6 are rejected under 35 U.S.C. 102(e) as anticipated by Lesh et al-6,152,144.

As to claims 1, 4-6, Lesh-'144 (Fig. 6-8, 11-12; C 2: L 2-6; C 9: L 15-42, for example) shows a occluding device for prevention of an embolic stroke caused by embolic material (blood clots, gas buble, solid tissue or the like, see C 4: L 18-20), in particular, formed in the left atrial appendage of a patient (abstract). Lesh-'144 device comprises mesh membrane 61/107, expandable support structure 65/103, which can be expandable by a balloon or by a

self expanding mechanism (col. 9, lines 15-42) and a method substantially as recited in the claims.

Especially, Lesh-'144's (F 3a, 6-8; col. 2, lines 42-45) disclose mesh membrane 61/107 having pores sized up to **0.005"** (or **0.127mm or 127 microns**) or pores sized up to **0.04"** (or **1mm or 1000 microns**). Inherently, mesh membrane 61/107 of Lesh-'144 must allow blood cells to flow through and filter any thrombus particles having a size bigger than the pore sizes (up to 127 microns or up to 1,000 microns) to go through.

Notice that blood red cells are about **6-8 micron or micrometers** and most white blood cells are about **10-12 microns** as indicated in two attachments: (1). *Red\_blood\_cell\_size.pdf*, and (2). *"White\_blood\_cell.pdf"*.

#### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lesh et al-6,152,144 in view of Bates-6,179,859 B1.

As to claim 1, Lesh-'144 (Fig. 6-8, 11-12; C 2: L 2-6; C 9: L 15-42, for example) shows a occluding device for prevention of an embolic stroke caused by embolic material (blood clots, gas bubble, solid tissue or the like, see C 4: L 18-20), in particular, formed in the left atrial appendage of a patient (abstract). Lesh-'144 device comprises mesh membrane 61/107, expandable support structure 65/103, which can be expandable by a balloon or by a self expanding mechanism (col. 9, lines 15-42) and a method substantially as recited in the claims. Especially, Lesh-'144's (F 3a, 6-8; col. 2, lines 42-45) disclose mesh membrane 61/107 having

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pores sized up to 0.005" (or 0.127mm or 127 microns) or pores sized up to 0.04" (or 1mm or 1000 microns).

Lesh-'144 does not **explicitly** state mesh membrane 61/107 for filtering emboli in a left atrial appendage sac in a patient. However, Bates-'859 (F 1-3E; C 4: L 30-38) discloses a filter sac 31 having pores preferably about 0.0012" (**30 microns**) to filter embolic material. It would have been obvious to one of ordinary skill in the art to provide mesh membrane 61/107 of Lesh-'144 having pore sizes of about 30 microns to filter embolic material formed in the left atrial appendage of a patient, as this configuration would filter embolic particles bigger than about 30 microns in the left atrial appendage of a patient from flowing through the filter membrane 61/107 of Lesh-'144 to the blood stream of a patient and prevent the patient from suffering an embolic stroke.

2. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lesh et al-6,152,144.

As to claim 7, Lesh-'144 discloses substantially a device and a method of preventing an embolic stroke substantially as recited in the claims except for removing the expandable structure through an opening in Lesh-'144's membrane 61 after expanding the support structure 65 (Fig. 6-8). However, Lesh-'144 (col. 9, lines 15-33) discloses a balloon to expand support structure 65 and a lumen with a self sealing valve in hub 73 for receiving a guidewire of guiding member (Col. 10, lines 3-8). The self sealing valve will prevent a passage of fluid or embolic material once the guidewire or guiding member is removed from the lumen. It would have been obvious to one of ordinary skill in the art to provide balloon catheter through the lumen in hub 73 to expand the support structure 65 and then withdraw the balloon from a left atrial appendage after the support structure 65 has been expanded by the balloon, as the lumen in hub 73 is the passage way available for introducing and removing the balloon catheter.

***Response to Arguments***

Applicant's arguments filed 4/5/2010 have been fully considered but they are not persuasive.

**Section 102 rejection:** the applicant argued that: "There is no discussion in Lesh permitting the blood to flow back and forth across the membrane of Lesh, and the pore size is insufficient to allow such transfer of material. The Examiner notes that there is a wide range of pore size discussed in Lesh but it is quite important to note that the material described by Lesh is expanded FTFE and multiple layers of material are bonded together to form a laminate so that none of the holes actually communicates across the structure. If one were to take a material of Lesh and place water on it, the water would bead up and remain on the surface and not flow through the membrane. Since the filtration feature required by the claim is not present in Lesh, Lesh does not anticipate the invention.".

As set forth above, the pore sizes of mesh membrane 61/107 of Lesh-'144 (up to 1000 microns) will filter thrombus particles because mesh membrane 61/107 inherently allows a blood flow to go through and inherently filter thrombus particles having sizes bigger than the pore sizes from going through the mesh membrane.

There is no indication in Lesh-'144 that membrane 61/107 are of multiple layers of materials bonded together and water would not flow through the mesh membrane.

***Conclusion***

The "Final Office Action" (paper 3/12/2009) has been withdrawn as new ground 112, 2<sup>nd</sup> paragraph rejection and new ground of 103(a) rejection of claim 1 have been introduced, old 103(a) rejection of claims 1, 4-6 has been withdrawn.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vy Q. Bui whose telephone number is 571-272-4692. The examiner can normally be reached on Monday-Tuesday and Thursday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vy Q. Bui/  
Primary Examiner, Art Unit 3773